

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/011086

International filing date (day/month/year)
01.04.2005

Priority date (day/month/year)
02.04.2004

International Patent Classification (IPC) or both national classification and IPC
A61M11/00, B05B17/06

DOCKETED FOR: 6/8/06 ✓

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...

COMPUTER *md*
BOOK *dc*
SCAN _____
CC: _____

1. This opinion contains indications relating to the following items:
 - Box No. I Basis of the opinion
 - Box No. II Priority
 - Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - Box No. IV Lack of unity of invention
 - Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - Box No. VI Certain documents cited
 - Box No. VII Certain defects in the international application
 - Box No. VIII Certain observations on the international application
2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.
3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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10/587814

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

AP20 Rec'd PCT/PTO 28 JUL 2006

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 in written format
 in computer readable form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,
 claims Nos. 58

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
 the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 no international search report has been established for the whole application or for said claims Nos. 58
 the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
the written form has not been furnished
 does not comply with the standard
the computer readable form has not been furnished
 does not comply with the standard
 the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
 See separate sheet for further details

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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
 - paid additional fees.
 - paid additional fees under protest.
 - not paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:
 - complied with
 - not complied with for the following reasons:

see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
 - all parts.
 - the parts relating to claims Nos. 1-25

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims 12-15
	No:	Claims 1-11,15-21,24,25
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-25
Industrial applicability (IA)	Yes:	Claims 1-25
	No:	Claims

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 58 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: *a method of using an aerosolizing device for administering an aerosolized agent to a patient*. For said claims no international search report has been established and, consequently, no examination will be carried out with respect to the novelty, inventive step and industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item IV

Lack of unity of invention

1. This International Preliminary Examination Authority considers that there are the following 3 (groups of) inventions claimed in the international application:
 - i) claims 1-25, which essentially define an aerosolizing element comprising a movable element being capable of moving in response to an external force;
 - ii) claims 26-41, which essentially define an aerosolizing device including a disposable aerosolizing element being removable from the housing of the aerosolizing device;
 - iii) claims 42-57, which essentially define an aerosolizing device including a disposable aerosolizing element, wherein the element prevents the agent to be expelled, from contacting an actuator.

These 3 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features are:

- between claim 1 and any of claims 26 or 42: a removable aerosolizing element capable of expelling an aerosolized agent ;
- between claims 26 and 42: an aerosolizing device comprising a housing, a disposable aerosolizing element capable of expelling aerosolized agent, an oscillator/actuator positioned to exert vibratory oscillations on a portion of the

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disposable aerosolizing element to aerosolize agent in the element, and a patient interface shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient.

An aerosolizing element and an aerosolizing device according to these features, however, are known from the document US2003/0164169 (see figures 4A-4C for example).

The features of each group which are not common with any of the other groups address different objective technical problems. Said problems may be regarded as being:

- i) how to provide dose of an agent for aerosolization, which can be stored and aerosolized in a convenient way;
- ii) how to provide a compact aerosolizing device;
- iii) how to prevent contamination of the aerosolizing device.

Consequently, the single general concept in the present case is not novel (and hence non inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

2. As the applicant had not paid the additional search fees this Authority has established the present written opinion on the basis of the first group of inventions, i.e. claims 1-25 (PCT Guidelines 17.60).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP-A-1 149 602 (MICROFLOW ENGINEERING SA) 31 October 2001 (2001-10-31)

D2: US-A-5 709 202 (LLOYD ET AL) 20 January 1998 (1998-01-20)

D3: US 2002/124852 A1 (GONDA IGOR ET AL) 12 September 2002 (2002-09-12)

1. The present application does not meet the criteria of Article 33(1) PCT, because the

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subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses a removable (column 10, lines 49-52) aerosolizing element (5) suitable for use in an aerosol delivery device (1), comprising:
a body (8, 18) having an exterior surface and a chamber (9) defined therein;
an inlet (7) defined in the body for connection to a source of agent, the inlet being in fluid communication with the chamber;
agent releasing orifices (14, 15) defined in the body in communication with the chamber; and
a moveable element (8, 8a) having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the outer surface to expel agent in the chamber through the orifices (column 7, lines 34-39).

All features of claim 1 are also known from document D2, see for example figure 10

2. Dependent claims 2-25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, see documents D1-D3 and the corresponding passages cited in the search report.

Re Item VII

Certain defects in the International application

1. The independent claim 1 is not drafted in the two-part form, as normally required by Rule 6.3(b) PCT.
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Claims 24 and 25 are not numbered as required by Rule 6.4(c) PCT.